

TESTIMONY OF MICHAEL MULVIHILL

United States Senate
Committee on the Health, Education, Labor and Pensions
Hearing on Protecting Patients from Defective Medical Devices
August 4, 2009

My name is Mike Mulvihill. I'm 64 years old and live in Bettendorf, Iowa. I had a Medtronic EnTrust defibrillator implanted on March 28, 2006 for irregular heart beat and pulse rate.

I had a life changing episode on Saturday, June 30, 2007. My wife Mary and I were driving to see our son, daughter-in-law, and grandchildren in Haddonfield, NJ. On Saturday morning I was driving east of Springfield, Ohio on I-70 at about 7:30AM in a construction zone when the device went off. I first thought we'd hit some road debris but could not understand the blue flash I'd seen. I navigated the car toward the shoulder of the road when the device shocked me again and I realized what was going on. As I made it to the shoulder of the road, Mary was calling 911. I don't remember how many times the unit went off – all I recall is the excruciating pain and the fear I was feeling.

The responders took me to a rural hospital in London, Ohio. As they rolled me in on a gurney the device went off again – lifting me off the gurney. I remember looking at a nurse whose eyes were really, really wide open with concern. My wife had to go outside to escape my loud and continuous screaming due to the pain. The hospital transported me to Ohio State University-Ross Heart Institute.

Upon check-in at Ross Heart Institute, a Medtronic rep came into the room and read the device. He told us it had shocked me 22 times in 53 minutes. He added that it was an electrical wire lead problem. One of the several doctors who came in the room told my wife and me how lucky we were that I had not wrecked the car.

A lead replacement surgery was scheduled for Monday, July 2, 2007 in the early afternoon. I was admitted for three days until I was discharged on Tuesday, July 3. Mary had to drive to my son's home and all the way back to our home.

After the episode, I found that driving on freeways/interstates made me very anxious, tense and fearful of the device going off again. This anxiety had a huge impact on me and my job. My job as a golf irrigation specialist covered 77 counties in Iowa, 17 in Illinois and 3 in Wisconsin. I could no longer cover these routes due to the anxiety I suffered any time I drove on the freeway.

My inability to drive long distances also affected my personal life. I had two fishing trips planned for the fall of 2007. These were annual fishing trips that I'd gone on for over 15 years. Both trips were impacted by the anxiety I was experiencing. The first trip was in the second week of September to Deer River, MN. One of my fishing buddies drove the entire distance up and back. While in Deer River, I was afraid the device was malfunctioning. I was experiencing chest pains so we went to an emergency room where the doctor concluded that I was likely suffering from ulcers. Upon returning home, my permanent doctor located the ulcers and placed me on medication.

The second week of October 2007 was the next fishing trip. Again, one of the fellows on the trip was kind enough to do all the driving to our Hayward, WI destination. I was only able to stay for 1½ days of the 9 day trip before nerves, anxiety, and fear got

to me. The same fellow drove me the 380 miles home then went back up to finish his vacation.

The anxiety that I feel, especially when traveling, has severely limited the number of trips Mary and I take to see family and friends. This anxiety has also limited Mary's travel since I worry more when she's not there to help calm me down.

I decided I needed professional help. I began seeing a psychologist who taught me some relaxation techniques. These exercises helped to calm me down. It was also at this time that I decided that the travels and pressure of my sales job were too much to handle, so I moved my retirement up to January 3, 2008. This was about a year and a half sooner than I had originally planned.

I had several device checks in 2008 and 3 trips to the ER within 6 months of the lead replacement. The majority of these visits were from me feeling that something was not right. One of my biggest questions is what effect the numerous shocks from the Medtronic device have had on my heart.

Any unexpected twinge or unusual feeling in the chest area makes me very tense. I begin to wonder if the device is working properly or whether I need to go to the hospital. It is not a fun way to live.

My hope is that no one else ever has to go through the pain and agony that I experienced with the fractured lead, and that Medtronic is held responsible for the injuries it has caused other patients like me.